UC San Diego Senior Associate Vice Chancellor for Health Sciences Office of Clinical Research	SOP Number	OCR:012 Page 1 of 3
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SOP TITLE: INVESTIGATIONAL PRODUCT HANDLING		

1 PURPOSE

1.1 This procedure describes the process for Principal Investigators (PIs) to follow when working with investigational drugs, biologics, devices and experimental procedures to ensure research utilizing these products is conducted in a manner that protects participant safety, rights, and well-being and complies with UC San Diego Health policy (UCSDHP) and applicable local and federal regulatory requirements.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 REQUIREMENTS

3.1 UCSDHP 341.1 Investigational Drugs, Devices, and Procedures describes institutional requirements for working with investigational products or procedures and states:

3.1.1 Research participants in a study with an investigational product must have a medical record created, with a signed copy of the informed consent/assent and HIPAA forms uploaded to the medical record.

3.1.2 Investigational drug/biologic studies that are conducted in UC San Diego Health licensed space must utilize services from the Investigational Drug Service (IDS) to receive, store, manage, and account for the drug/biologic. Contact IDS via email at CTRI-IDSPharm@ucsd.edu.

3.1.3 For investigational drug/biologic studies that are conducted in UC San Diego Health non-licensed space, the PI may elect to manage the investigational product or to utilize the services of the IDS. If the PI elects to manage the product, the PI remains responsible for following all applicable UCSDHP and regulatory requirements, including those detailed in section 5.2 below) and specifically:

3.1.3.1 Adhering to FDA requirements in 21 CFR Part 312, Subpart B, which includes obtaining Investigational New Drug (IND) approval and following protocols for drug administration and monitoring

3.1.3.2 Keeping detailed records of drug receipt, storage, dispensing, and administration.

3.1.3.3 Storing and handling the investigational product according to the manufacturer's specifications, study protocol, and regulatory guidelines.

3.1.3.4 Implementing safety monitoring procedures for assessing, documenting, and reporting adverse events.

3.1.3.5 Complying with all regulatory requirements, institutional policies, and state and federal regulations.

3.1.4 For investigational device studies, the PI may manage the device but must comply with UCSDHP and applicable regulatory requirements for medical device investigations at 21 CFR 812 Investigational Device Exemptions, including requirements for labeling, storage, and accountability.

3.1.5 Research studies with a medical procedure that is significantly different from standard of care must be reviewed by the PI's department chair, in addition to IRB review, to evaluate whether the proposed procedure requires additional authorization or oversight.

3.1.6 Research using radiopharmaceuticals must utilize services from Nuclear Medicine to control the radiopharmaceutical product. Clearance from all applicable ancillary committees must also be obtained.

3.1.7 Investigational products may only be administered with the written order or prescription from the PI or appropriately qualified designee as described in UCSDHP 321.3 Patient Treatment and Medication Orders. For investigational drug dispensing, the designee must be listed on the FDA Form 1572.

4 RESPONSIBILITIES

4.1 The PI is responsible for ensuring safe and compliant management of investigational products and for prescribing, dispensing, or using investigational products only with study participants who are qualified to receive them according to the study protocol.

4.2 The PI is responsible for ensuring the investigational product is used only in the manner prescribed by the study protocol.

4.3 The PI is responsible for ensuring that study records accurately reflect the investigational product use in research participants and that reconciliation records for investigational products are maintained.

5 PROCEDURE

5.1 Investigational Drug/Biologic in UC San Diego licensed space:

5.1.1 The PI or designee confirms and documents participant eligibility to receive the study drug/biologic according to the protocol eligibility requirements.

5.1.2 The PI or designee should follow the steps in section IV of UCSDHP 341.1 Investigational Drugs, Devices and Procedures.

5.2 Investigational Drug/Biologic in UC San Diego non-licensed space:

5.2.1 The PI or designee confirms and documents participant eligibility to receive the study drug/biologic according to the protocol eligibility criteria.

5.2.2 If the PI elects to utilize IDS services, the steps in section IV of UCSDHP 341.1 Investigational Drugs, Devices and Procedures should be followed.

5.2.3 If the PI elects to manage the investigational drug/biologic themselves, steps 2 through 5 in section V.A. of UCSDHP 341.1 Investigational Drugs, Devices and Procedures apply. The PI or designee must maintain accurate dispensing and accountability logs using e.g., OCR-109(a-c) Investigational Product Accountability Log, or equivalent.

5.3 Investigational Device:

5.3.1 Upon receipt of the investigational device, the PI or designee will maintain a master device accountability log that records the receipt, device identifying details (e.g., lot or

serial number), manufacturing and/or expiration dates, and other relevant information. The records may be maintained on OCR-109(a-c) Investigational Product Accountability Log, or equivalent.

5.3.2 The PI or designee must ensure that the devices are securely stored and that all temperature and environmental storage conditions meet protocol requirements.

5.3.3 Prior to dispensing a device to or using a device with a research participant, the PI or designee will ensure that the participant is qualified to receive the device or treatment according to the study protocol eligibility criteria.

5.3.4 The PI or designee will record details for each participant on whom the device was used or to whom it was dispensed.

5.4 Investigational Product Accountability Records:

5.4.1 Investigational product accountability records and details of investigational product use, including study participant records, must be retained as required by regulations and/or sponsor requirements.

6 MATERIALS

6.1 OCR-109(a-c) Investigational Product | Drug | Device Accountability Log Templates

7 REFERENCES

7.1 UCSDHP 341.1 Investigational Drugs, Devices, and Procedures

7.2 UCSDHP 321.3 Patient Treatment and Medication Orders

7.3 21 CFR 812 Investigational Device Exemptions

7.4 FDA Form 1572